

REMARKS

Objection to Claims

Claims 4-14 and 18-20 are objected to under 37 C.F.R. Section 1.75(c) as being in improper form because “.... a multiple dependent claim cannot depend from any other multiple dependent claim....” It is respectfully believed that all objected Claims do not directly or indirectly refer to more than one multiple dependent claim. As defined in the *Manual for Patent Examining Procedure*, Section 608.01(n), Page 600-71: “Generally a multiple dependent claim is a dependent claim which refers back **in the alternative to more than one** preceding independent **or dependent claim.**”

Specifically, Claim 1 is an independent claim, Claim 2 solely depends on Claim 1 and Claim 3 solely depends on Claim 2. Claim 4 is a multiple dependent claim that refers in the alternative to Claims 1, 2 or 3. Therefore, with Claim 4, there is no multiple dependent claim that depends from another multiple dependent claim. There is just one multiple dependent claim that refers to a prior independent claim and two prior dependent claims that each have a **single, solitary dependency**. Claims 5, 9 and 11 are just like Claim 4 with regard to depending from Claims 1, 2, or 3. Claims 6 and 7 depend from Claims 4 and 5, respectively. Once again, there are **no two multiple dependent claims** in the chain either directly or indirectly. Claims 8 and 12 each depend from Claim 2, which depends from Claim 1. There is not even a single multiple dependent claim linked to Claim 8. Moreover, there is not a single multiple dependent claim linked to Claim 12. Claim 10 solely depends from Claim 9, which is the only multiple dependent claim in the chain. Claims 13 and 14 are dependent claims that depend solely from independent Claim 1. There is not even a single multiple dependent claim in the chain for either

of these claims. Claim 18 is a multiple dependent claim that depends from Claim 16 (independent claim) and Claim 17 (dependent claim that solely depends from Claim 16). Once again, there are no two multiple dependent claims in the chain either directly or indirectly linked. Claim 19 solely depends from Claim 3, which solely depends from Claim 2, which solely depends from independent Claim 1. There is not even a single multiple dependent claim in the linking chain for Claim 19. Claim 20 solely depends from Claim 19.

Therefore, it is respectfully believed Claims 4-14 and 18-20 do not directly or indirectly refer to more than one multiple dependent claim and the objections under 37 C.F.R. Section 1.75(c) are overcome.

Rejection under 35 U.S.C. Section 103

Claim 1 was rejected under 35 U.S.C. Section 103 as being unpatentable over Apple et al. (U.S. Patent No. 6,494,824), in view of Reich (U.S. Patent No. 6,425,174) and further, in view of Gleason et al. (U.S. Patent No. 5,032,719).

Apple et al. discloses a **single, solitary container** and does not disclose a "...a first container, a second container and shielding means, wherein the first container is provided with first sealing means for liquid and gas tight closing the first container, wherein the second container is provided with second sealing means for liquid and gas tight **enclosing the first container within the second container...**" (Applicant's Claim 1).

Apple et al. in Column 24, Lines 30-46 discloses: "FIG. 56 is a partially section view side view of the vial of FIG. 54 in **which radioactive fluid container 701** is inside an outer shield 720 and loaded into the injection apparatus 751 (FIG. 58). The outer shield 720 is typically

made of lead for protection during handling and use and provides both a safe shipping container as well as shielding for the operator during treatment. The **outer shield 720 includes a proximal end cap 746 that is removed** for loading of the radioactive fluid container 701. The end cap 746 is press-fitted into the outer shield 720 to provide additional shielding to aid in creating a close fit within a carriage 725. The end cap 746 includes **an opening 722** through which the external control mechanism 706 is inserted for engagement with radioactive fluid seal 702. The opposite end of the outer shield 720 includes **a second opening 721** through which the needle cannula 734 accesses the septum 707 of the radioactive fluid container 701." Therefore, it is respectfully believed that there is a single, solitary radioactive fluid container. **There are openings 722 and 721 at each end** which provide access so that there are no two containers that are liquid and gas sealed and enclosed within each other. Moreover, Apple et al. discloses in Column 5, Lines 66-67 and Column 6, Lines 1-15 as follows: "FIGS. 1 to 6 disclose the preferred embodiment of a medical radiation treatment system 10 of the present invention which includes a medical radiation treatment device 14 that is connectable to a radioactive fluid delivery device such as balloon catheter apparatus 20. With reference to FIGS. 52 and 53, **medical radiation treatment device 14** includes a sealed source of radioactive fluid, preferably gas 12, which is contained in a sealed, **preferably fluid or gas-tight, container 15**. The gas-tight container 15 in one aspect of the invention is a commercially available, 3 cc, sealed vial with a gas-tight seal membrane 16 at one end thereof for accessing the radioactive gas. The gas-tight seal or membrane is punctured with a piercing cannula or needle so as to permit the radioactive gas in the vial to flow therefrom to the delivery device such as balloon catheter apparatus 20. The fluid or gas-tight container 15 can have an interior volume 17 ranging in size

from 0 to 10 cubic centimeters.” Therefore, it is respectfully believed that the radioactive fluid container 701 is but one single, solitary container that provides a different embodiment than the sealed container 15 shown in FIG. 52. These are two separate containers for different embodiments and do not represent two gas and liquid sealed containers enclosing each other.

Reich is cited for disclosing a pharmaceutical pig and is directed in the Office Action to Claim 12. Gleason et al. is cited for disclosing a portable dosimeter calibration device and is directed in the Office Action to Claims 19 and 20.

Therefore, a first container, a second container and shielding means, wherein the first container is provided with first sealing means for liquid and gas tight closing the first container, wherein the second container is provided with second sealing means for liquid and gas tight enclosing the first container within the second container **is not disclosed**. It is respectfully believed to be axiomatic that features that are not disclosed in any of three (3) cited References cannot come into being by their combination. Moreover, it is respectfully believed that all claim limitations must be considered. In this case, Apple et al., Swan and Gleason et al. do not disclose dual containers sealed for liquid and gas leakage and enclosed within each other. It is now a basic tenet of patent law that the results and advantages produced by the claimed subject matter, of which the prior art is devoid, cannot be ignored simply because the claim limitations are similar to the otherwise barren prior art. It is respectfully believed that patentability of the claimed subject matter must be determined in view of the invention “as a whole.” In this case, Applicant’s Specification, Published International Application PCT/US00/04853, Page 2, Lines 9-24 recites: “When the first container, for example a glass vial, is damaged, for example by inappropriate handling of the holder, the radioactive substance cannot reach the shielding means

since the substance will be contained within the essentially unbreakable second container. Since this second container is gas and liquid tight, the substance cannot leave the second container. Thus the shielding means do not necessarily have to be air and liquid tight, nor do these shielding means have to be contained within a further air and liquid tight containing means such as a tin known from the prior art. Since the first and second liquid and air tight containers are provided within the shielding means, a holder according to the present invention is very safe and easy to use, relatively small with respect to the inner dimensions of the first container and relatively economical in use." These aspects and advantages are not disclosed in either Apple et al., Swan or Gleason et al.

It is respectfully believed that the test is whether it would have been obvious to one of ordinary skill in the art given the teachings of the prior art reference. In this case, Apple et al. teaches a catheter apparatus and a radiation dosimetry unit indicator. There is a single **radioactive fluid container 701** with an end cap 746 at one end that includes **an opening 722** through which the external control mechanism 706 is inserted for engagement with radioactive fluid seal 702. The opposite end of the outer shield 720 includes **a second opening 721** through which the needle cannula 734 accesses the septum 707 of the radioactive fluid container 701. Therefore, two containers where the first container is provided with first sealing means for liquid and gas tight closing the first container and the second container is provided with a second sealing means for liquid and gas tight enclosing the first container within the second container is not disclosed.

Therefore, there is no recognition of the problems faced by the Applicant, i.e., breaking or opening of the inner container as well as ease of use, and as result, one skilled in the art would

not likely consider Apple et al., Swan or Gleason et al. and any combination thereof in an attempt to solve such a problem. It is respectfully believed ever since Eibel Process Co. v. Minnesota and Ontario Paper Co., 261 U.S. 45 (1923), that the Federal Court of Appeals for the Federal Circuit as well as the United States Patent Office has recognized the longstanding rule that discovery of the source of the problem is patentable even if the solution is deemed obvious (which is not the present situation).

Therefore, Claim 1 overcomes the rejection under 35 U.S.C. Section 103 as being unpatentable over Apple et al. in view of Reich and further in view of Gleason et al..

Claims 2-15 were also rejected under 35 U.S.C. Section 103 as being unpatentable over Apple et al. in view of Reich and further in view of Gleason et al. Since Claims 2-15 depend from and contain all of the limitations of Claim 1, Claims 2-15 are felt to distinguish from Apple et al. in view of Reich and further in view of Gleason et al. in the same manner as Claim 1.

Moreover, Applicant's Claim 12 discloses: "...wherein the shielding means comprises a third container and at least a fourth container, the fourth container forming at least part of storage and/or transporting means for the further containers." Reich is cited for providing a third and fourth container. Reich in the Abstract, Lines 1-18 discloses: "A method and apparatus for transporting syringes containing radioactive material. The apparatus includes a radiopharmaceutical pig having an inner chamber in which a sharps container can be secured. The sharps container has a housing and an attachable cap. The method includes assembling the radiopharmaceutical pig so that the chamber of the radiopharmaceutical pig contains the syringe in the sharps container housing. The radiopharmaceutical pig is disassembled, where upon the syringe is removed, discharged, and then replaced in the sharps container housing. The cap of

the sharps container is affixed to the housing of the sharps container, thus enclosing the contaminated syringe therein. The radiopharmaceutical pig is assembled so that its chamber contains the sharps container and the syringe. The radiopharmaceutical pig is transported to a disposal area, where it is disassembled and the sharps container containing the syringe is placed in a particular disposal container." Therefore, this is merely a radiopharmaceutical pig for storing and holding a syringe. Neither Reich nor Apple et al. disclose a first container, a second container and shielding means, wherein the first container is provided with first sealing means for liquid and gas tight closing said first container, wherein the second container is provided with the second sealing means for liquid and gas tight enclosing the first container within the second container. It is respectfully believed to be axiomatic that when claimed elements are not disclosed in either of two elements, they cannot come into being by their combination.

Moreover, Reich **teaches away** by reciting that: "Yet another advantage of the present invention is the prevention of the contamination of the radiopharmaceutical pig 10. During the transport of the syringe 14 to the hospital, the housing of the sharps container 12 advantageously prevents the inner cavity of the lower shield of the radiopharmaceutical pig from becoming contaminated. **If the syringe leaks, the radioactive drug collects above the closed end 64 of the housing 26**, thereby preventing the contamination of the inner cavity of the lower shield 18. Furthermore, once the spent syringe is sealed within the sharps container, the inner cavities of the upper 16 and lower 18 shield are advantageously protected from contamination while the radiopharmaceutical pig is moved to the disposal area."(Column 12, Lines 23-35). Therefore, it is expected that the device, i.e., syringe (which is not a dual enclosed containers) placed in the radiopharmaceutical pig 10 of Reich will leak. This directly negates the presence of "...the first

container is provided with first sealing means for **liquid and gas tight closing the first container**, wherein the second container is provided with second sealing means **for liquid and gas tight enclosing the first container within the second container.**” Therefore, Reich is designed for containing a leaky syringe and someone with ordinary skill in the art would not consider this Reference when working with two containers that are both liquid and gas tight and sealed within each other. The Supreme court held in U.S. v. Adams, 383 U.S. 39, 148 U.S.P.Q. 479 (1966), that one important indicium of nonobviousness is “teaching away” from the claimed invention by the prior art or by experts in the art at (and/or after) the time the invention was made. In this case, a radiopharmaceutical pig that is designed to handle syringe leakage would not be used with two containers that do not leak gas, much less liquid.

Furthermore, what is obvious is that which can be deducted by a logical step-by-step reasoning process from the premises furnished by the prior art. In this case, there is not the slightest hint or suggest to combine the catheter apparatus and radiation dosimetry disclosed in Apple et al., which does not disclose **two liquid and gas sealed containers located within each other** with a radiopharmaceutical pig disclosed in Reich. Not only would you not arrive at the claimed invention, but also there are simply no teachings where someone with ordinary skill in the art could attempt to arrive at the Applicant’s claimed Invention. There must be a reason to modify the reference and this reason to modify the reference must be based on objective evidence of record. A showing of a suggestion, teaching or motivation to combine the prior art references is an essential component of an obviousness holding. C. R. Bard, Inc. v. M3 Systems, Inc., 48 U.S.P.Q.2d 1225, 1232 (Fed. Cir. 1998). In this case, any suggestion, teaching or motivation to combine the prior art references is wholly absent.

Therefore, Claim 12 overcomes the rejection under 35 U.S.C. Section 103 as being unpatentable over Apple et al. in view of Reich and further in view of Gleason et al.

Claim 16 was also rejected under 35 U.S.C. Section 103 as being unpatentable over Apple et al. in view of Reich and further in view of Gleason et al. In addition to all of the limitations of Claim 1, Claim 16 includes a shielding means that forms a third container. Apple et al. in Column 7, Lines 1-14, as follows: "FIG. 53 depicts an enlarged pictorial view of medical radiation treatment device 14 of FIG. 1 including a **sealed, gas-tight container 15** with a gas-tight plunger 18 or gas-tight plunger base positioned opposite the distal end thereof for pushing radioactive fluid 12 from interior volume 17 of the container when as valve 13 is operated to the open position. The gas-tight valve can be a separate component that is attachable to the container or can be integrated into the container. This embodiment of sealed container 15 provides for a much more complete evacuation of the radioactive fluid in interior volume 17. In addition, the **container walls can have varying degrees of glass/plastic radiation shielding** for alternating higher radiation activity levels." Therefore, there is a **single container having shielded walls**. Consequently, the Applicant's claimed device with three containers that are enclosed within each other is a markedly different device. It is respectfully believed that all claim limitations must be considered. Under the patent statute, Title 35 U.S.C., "ideas" are not patentable; claimed structures and methods are. Reducing a claimed invention to an "idea" and then determining the patentability of that "idea" is respectfully believed to be an error. Analysis properly begins with the claims for they measure and define the invention. Jones v. Hardy, 727 F.2d 1524, 220 U.S.P.Q. 1021 (Fed. Cir. 1984). In this case, the three sealed containers, as

recited in Claim 16 are wholly absent from either Apple et al., Reich or Gleason et al. and any combination thereof.

Moreover, it is only with hindsight based on reviewing the Applicant's patent specification that someone would create three containers based on a reference that only recites one container. It is respectfully believed that hindsight is not the test of obviousness nor is it alone sufficient that other devices might have been adapted without too much difficulty to produce the object and function of Applicant's claimed device.

Therefore, Claim 16 overcomes the rejection under 35 U.S.C. Section 103 as being unpatentable over Apple et al. in view of Reich and further in view of Gleason et al.

Claims 17 and 18 were also rejected under 35 U.S.C. Section 103 as being unpatentable over Apple et al. in view of Reich and further in view of Gleason et al. Since Claims 17 and 18 depend from and contain all of the limitations of Claim 16, Claims 17 and 18 are felt to distinguish from Apple et al. in view of Reich and further in view of Gleason et al. in the same manner as Claim 16.

Claims 19 and 20 were also rejected under 35 U.S.C. Section 103 as being unpatentable over Apple et al. in view of Reich and further in view of Gleason et al. Since Claims 19 and 20 depend from and contain all of the limitations of Claim 1, Claims 19 and 20 are felt to distinguish from Apple et al. in view of Reich and further in view of Gleason et al. in the same manner as Claim 1. Furthermore, Gleason et al. would destroy the Applicant's Invention for its intended function and purpose since the Applicant's Invention discloses two containers that are both liquid and gas tight enclosed within each other. In marked contrast, Gleason et al. recites in Column 6, Lines 4-11 as follows: "As also seen in FIG. 5, the radiation emanating upwardly

from source 102 is shielded by the source stop plug 106 and by the metal of the source rod 14 that lies **between the access apertures 104** and the slot 87. Clearly, if desired, the upper section of the source rod 14 can be filled with, or formed from lead. Radiation emanating downwardly is shielded by the base shield 64.” Therefore, there are **openings disclosed in Gleason et al.** that would destroy the fluid and gas tight seals required in the Applicant’s Invention as claimed. It is respectfully believed that Gleason et al. is not properly modifiable if this intended function of Gleason et al. is destroyed since one of ordinary skill in the art would not have any motivation to make this modification and, in fact, would be specifically motivated not to make this modification.

Therefore, Claims 19 and 20 are clearly and patentably distinguishable over Apple et al. in view of Reich and further in view of Gleason et al.

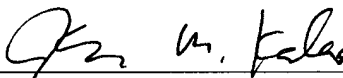
It is now believed that all of the pending claims in the present application, namely, Claims 1-20 are in condition for allowance. Favorable action and allowance of the claims is therefore respectfully requested.

Amendment A
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If any issue regarding the allowability of any of the pending claims in the present application could be readily resolved, or if other action could be taken to further advance this application such as an Examiner's amendment, or if the Examiner should have any questions regarding this amendment, it is respectfully requested that the Examiner please telephone the Applicant's undersigned attorney in this regard.

Respectfully submitted,

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